



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
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Michael Fromm, PhD
Epicrop Technologies, Inc
5701 N 58th St
Lincoln, NE 68507

Re: APHIS confirmation of the regulatory status of soybean null segregant (NS) plants derived from genetically engineered (GE) plants in your breeding program.

Dear Dr. Fromm:

Thank you for your letter of inquiry dated January 3, 2017. Your letter inquired about the regulatory status of soybean (*Glycine max*) null segregant (NS) lines derived from genetically engineered (GE) parental plants in your breeding program. The NS lines and their progeny will ultimately be used for field tests and interstate movement.

The Plant Protection Act (PPA) of 2000 gives USDA the authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds to protect the agriculture, environment, and economy of the United States. The APHIS mission is to protect the health and value of American agriculture and natural resources.

APHIS regulates the environmental release of certain genetically engineered organisms which are, or have the potential to be plant pests. Regulations for genetically engineered organisms that have the potential to be plant pests, under the Plant Protection Act, are codified at 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason To Believe Are Plant Pests." Pursuant to the provisions of these regulations, a GE organism is deemed a regulated article if it has been genetically engineered from a donor organism, recipient organism, or vector or vector agent listed in §340.2 and the listed organism meets the definition of "plant pest" or is an unclassified organism and/or an organism whose classification is unknown, or if the Administrator determines that the GE organism is a plant pest or has reason to believe is a plant pest.

In your letter of January 3, 2017, you describe your breeding method, the resulting soybean NS plant lines, and the PCR-based analysis of soybean NS lines to verify the absence of transgenic fragments. As described, the GE parent plants were produced by *Agrobacterium*-mediated transformation and some of the inserted DNA was derived from plant pests, for example, Cauliflower mosaic caulimovirus. You also describe how the NS lines were developed by selecting the non-GE progeny of the GE parent plants, and how you verified the lack of any inserted genetic material in the NS lines by PCR analysis.

Based on the information provided in your January 3, 2017 letter, APHIS has determined that your NS soybean lines do not contain any inserted genetic material. APHIS also has no reason to believe that soybean is a plant pest. Therefore, consistent with previous

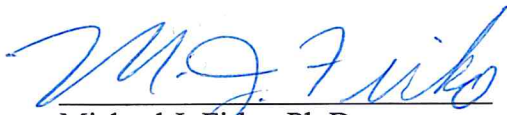
responses to similar letters of inquiry, APHIS does not consider the NS soybean lines described in your January 3, 2017 letter to be regulated pursuant to 7 CFR part 340. Additionally, soybean is not listed as a Federal noxious weed pursuant to 7 CFR part 360, and APHIS has no reason to believe that the increased yield trait will increase the weediness of soybean.

As described, APHIS would not consider the NS lines created via your breeding method to be regulated articles. However, please be aware that, as described in your letter, the GE parent plants are regulated articles because a plant pest vector was used to introduce DNA containing plant pest sequences. Therefore, the GE parent plants require an authorization for interstate movement or field release. Any unauthorized release of these GE plants could be a violation of our regulations at 7 CFR par 340.

Please be advised that the use of these same NS lines may still be subject to other applicable regulatory authorities such as EPA and FDA.

Should you become aware at any time of any issues or additional information that may affect the Agency's conclusion regarding this inquiry; you must immediately notify the Agency in writing of the nature of the issue. We hope you appreciate our commitment to plant health and support for the responsible stewardship for the introduction of GE plants.

Sincerely,



Michael J. Firko, Ph.D.
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture



Date